UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	**MDL # 1456**
	)	**Master File No. 1:01-CV-12257-PBS**
	)	**Sub-Category Case No. 1:08-CV-11200**
	)	**Judge Patti B. Saris**
THIS DOCUMENT RELATES TO ***United States ex rel. Linnette Sun and Greg Hamilton, Relators v. Baxter Healthcare Corporation***	)	

RELATORS' MEMORANDUM IN OPPOSITION TO DEFENDANT BAXTER HEALTHCARE CORPORATION'S MOTION FOR PARTIAL SUMMARY JUDGMENT

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I. INTRODUCTION

Ven-A-Care and Baxter reached settlement in October 2011 of Ven-A-Care's long-running pricing allegations against Baxter. This Court approved the settlement on October 17, 2011, and dismissed Ven-A-Care's claims against Baxter with prejudice on October 19. Baxter filed its motion for summary judgment in this case less than two weeks later, on October 19. It strains credulity to suppose that Baxter's finding itself filing summary judgment in this matter was a happy accident resulting from one last read-through of the settlement agreement: Rather it is obvious that Baxter sought to construct and spring a trap to maneuver itself out of liabilities which had nothing to do with the claims asserted against it by Ven-A-Care.

The United States has made it clear that it never consented to release claims for Advate, which are not present in the Ven-A-Care complaint.

Baxter's motion reduces to the proposition that it and Ven-A-Care hoodwinked the United States into releasing its claims for Advate. This remarkable claim is without a shred of support from Ven-A-Care and has no basis in fact.

Relators Sun and Hamilton demonstrate in the pages which follow that the False Claims Act is not as subject to facile manipulation as Baxter would have the Court believe. It is a simple fact that the drug Advate, which is the principal focus of the complaint in this matter, was not implicated in the Ven-A-Care claims, and Baxter has judicially admitted that Relators Sun and Hamilton filed the first, and only, claims against it in connection with its cynical manipulation of the wholesale price to public payers of Advate. Remarkably, Baxter concedes that Ven-A-Care never sued it with respect to its pricing of Advate (an inexorable conclusion, given the law of the

case), and it is a fact that the word "Advate" does not appear in the settlement agreement. Baxter nonetheless would have the Court conclude that the United States knowingly waived and released the claims asserted in this case without any notice to Ms. Sun and Mr. Hamilton by virtue of the inclusion "labeler code 00944," which begins the NDC numbers associated with a category of pharmaceutical products including numerous Baxter products, one of which is Advate.[1]

These propositions are not a tenable basis for summary judgment, and are, moreover, not remotely plausible. The Ven-A-Care settlement with Baxter has nothing to do with Advate. Baxter's motion is too clever by half, and it should be denied forthwith.

Baxter's argument that generalized knowledge of AWP manipulation means that the government knew of and acquiesced in Baxter's mega-spreads is similarly far-fetched. We explain that there is no evidence to suggest that the Medicaid programs knew that the spread on Advate and Recombinate was nearly twice the acquisition cost of these drugs.

Finally, we explain why Ven-A-Care's release of its claims about Recombinate are qualitatively different from the Sun/Hamilton claims.

II. ARGUMENT

A. Ven-A-Care lacked the capacity to settle claims relating to Advate pricing, because its complaint did not include allegations relating to Advate.

The Court has held that in the wholesale-pricing context, '[n]otice of fraud in one drug's pricing is not notice of fraud in another drug's pricing . . . . For this reason, this Court has

[1]Labeler Code 00944 includes the following Baxter products: Aralast; Gammagard; Gammagard Liquid; Glassia; Ceprotin; Tiseel; Artiss; TachoSil; Monarc-M; Recombinate; Hemofil M; and Advate. Of these drugs, all but Advate and Monarc-M, which was only recently acquired by Baxter, are identified in the Ven-A-Care complaint.

required plaintiffs to plead the allegedly fraudulent average wholesale price of each drug with specificity under Rule 9(b)." *In re. Pharm. Indus. AWP Litigation*, 293 F.Supp.2d 172, 194 (D. Mass. 2003). *A fortiori*, for the "allegedly-fraudulent average wholesale price of each drug" to be plead, the drug must itself be identified. However, no Ven-A-Care complaint filed in this matter has identified Advate as a fraudulently-priced drug.

On the other hand, Advate is, and always has been, the central focus of the complaint in this case. Ms. Sun alleges that:

> In July, 2002, Ms. Sun learned of a pricing report for Advate prepared by Simon Kucher & Partners, an international marketing consulting firm. Kucher & Partners recommended that to secure market share for Baxter had spent approximately $750,000 for a marketing study for this new product. In order to secure market share Baxter decided to sell Advate for $0.99 per dose, but to report an AWP of $1.60. Ms. Sun voiced her concern to Nick Poulios, John Park, and the VP of Global Marketing. When she warned that Baxter could get into trouble John Park joked that it was all an "innocent" mistake.

Amended Complaint, Doc. 7228, at ¶ 44. In a prior Order, this Court found that "[f]or both Advate and Recombinate, relators have alleged the fraudulent scheme and alleged both the fraudulent published prices and the actual prices, and thus the spread, for both drugs. This is sufficient to satisfy the pleading requirements of Fed. R. Civ. P. 9(b)." MDL Doc. 7008 at 5 (Order of March 25, 2010). The Court further found that Ms. Sun is an original source with respect to Baxter's Advate fraud:

> Here, Sun had direct and independent knowledge of essential information that she provided to the government before filing. Sun was intimately involved with the pricing of Baxter's drugs, specifically Advate. She was present when Baxter hatched its alleged plan to report its AWP disguised as its "list sales price" in the face of FDB's requirements. She saw documents which she

> said contained false prices. She also informed her superiors of the results of the false reporting, and was ordered to drop the issue. Although Sun did leave Baxter before Baxter began reporting information on Advate to FDB and other compendia, she left a mere week before, and thus was privy to much essential information. Sun has direct and independent knowledge of both the formation of Baxter's pricing scheme and Baxter's knowledge of its effects, 'essential element[s] of the underlying fraud transaction.' She thus qualifies as an original source.

Id. At 9.

Given that the United States never consented to a release of claims for Advate, and that the Ven-A-Care complaint does not even include the word "Advate" while Ms. Sun's complaint is fulsome in its description of Baxter's fraud relating to that drug, it is unsurprising that Baxter has judicially admitted that Ms. Sun and Mr. Hamilton are the first-filed relators with respect to that drug. On July 29 when, parenthetically, Baxter and Ven-A-Care were deep in settlement negotiations Baxter filed a motion to dismiss Relators' claims regarding Recombinate based on the argument that Ven-A-Care's complaint included Recombinate and triggered the first-to-file provision of the False Claims Act, 31 U.S.C. § 3730(b)(5).

On the first page of its memorandum supporting its motion to dismiss (Doc. 7831-1), Baxter asserts that "[o]nly Sun's False Claims Act ("FCA") allegations regarding Advate should be the subject of any further litigation." Baxter argues that "the Ven-A-Care and Sun/Hamilton complaints allege facts that give rise to identical recovery *concerning Recombinate*" (*id*. at 10 n.9 (emphasis supplied)) and concedes in its conclusion that, were it granted all the relief it sought, "Advate will be the sole Baxter therapy remaining in this litigation." *Id*. at 11.[2] And midway

[2] "A party's assertion of fact in a pleading is a judicial admission by which it normally is bound throughout the course of the proceeding." *Bellefonte Reins. Co. v. Argonaut Ins. Co.,* 757 F.2d 523, 528 (2d Cir. 2985), *quoted in Schott Motorcycle Supply, Inc. v. Am. Honda Motor Co.,* 976 F.2d 58, 61 (1st Cir. 1992).

through its brief, Baxter makes clear that it does not assert that Advate was included in the Ven-A-Care case:

> Both Ven-A-Care and Sun/Hamilton name Recombinate as one of the Baxter therapies involved in the alleged FCA scheme. See Ex. 3 (Ven-A-Care Complaint, Exhibit 6) at pp. 97-98; Sun/Hamilton Complaint (Ex. 1) ¶¶ 20, 36. This Court previously held that **the same specific drug must be named in both complaints to trigger the first-to-file bar** because "drugs are often marketed, reimbursed, sold, and priced in different ways." Abbott Labs., 2008 WL 2778808, at *3. Because Ven-A-Care identified Recombinate as one of the Baxter therapies covered by its false claims allegations in 2002,5 over two years before the Sun/Hamilton Complaint, Sun/Hamilton cannot assert claims about the same therapy. The Ven-A-Care and Sun/Hamilton complaints clearly contain the same "essential facts," as well as many supporting details, **relating to the false claims allegations concerning Recombinate.**

Id. at 6 (emphasis supplied).

By virtue of these concessions, Baxter's summary-judgment motion has focused this Court's inquiry on one precise question: Can a *qui tam* relator who is litigating a declined case on behalf of the United States settle allegations which do not exist in his or her complaint?

This process begins, as relevant here, with the decision by the United States not to intervene: "If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action." 31 U.S.C. § 3730(c). Not surprisingly, it is the position of the United States, stated in correspondence to the parties when it declines to intervene in a *qui tam* case, that it "will release the defendant only for civil monetary liability for the specific allegations of the complaint." But this statement is not mere governmental preference. Rather, it is rooted in the practical considerations which underlie the False Claims Act's *qui tam* enforcement mechanism and, ultimately, in the constitutional underpinnings of the authority of

the political branches, under the "take care clause," Art. I, Sec. 3, to delegate enforcement authority to non-governmental actors.

These principles are described in *United States v. Health Possibilities, P.S.C.*, 207 F.3d 335 (6th Cir. 2000). After the government declined to intervene in that case, the relator settled with the defendant for "injunctive relief," and collected attorney fees on the False Claims Act case and significant damages on an unrelated tort case against the defendant. The court noted that absent the requirement that the executive consent to a settlement, "the public interest would be largely beholden to the private relator" who could otherwise "broadly bargain away government claims." *Id*. at 341. Moreover, "[t]he recovery division requirements of the FCA provide further incentive for the over-broad release of government claims." *Id*. In another case, the Sixth Circuit observed, "[O]ne of the purposes of the FCA's grant of veto power to the government over voluntary dismissals is to prevent the relator from bargaining away government claims for the relator's sole gain." *United States ex rel. Smith v. Lampers*, 69 Fed. Appx. 719, 722 (6th Cir. 2003) (reversing dismissal with prejudice to which the United States did not consent). *Accord*, *United States ex rel Gibeault v. Texas Instruments Corp.* 104 F.3d 276 at 277 (9th Cir. 1997).

Here, there is no dispute that the Justice Department consented to the dismissal *of Ven-A-Care's claims* <u>*and nothing more*</u>. It is also apparent that Ven-A-Care had no claims relating to Advate. Anytime there is a settlement, the defendant will want to pay as little as possible for the broadest release it can get. It is also apparent that once a *qui tam* relator has negotiated a settlement amount, scope-of-release issues fade in significance from her perspective: Perforce, the *relator* is free to give as broad a release as she wishes, while it is the release of the United

States which is of critical importance to the defendant, to the public fisc and to the integrity of the *qui tam* system itself. It would be the simplest of matters for a relator to file a narrow lawsuit and then, after declination, accept a defendant's invitation to enter into a release broader than her allegations; but Congress guarded against this by precluding the dismissal of a claim without the consent of both the United States and the Court (31 U.S.C. § 3730(b)(1)). And the Department of Justice, in turn, guards against it by its practice, followed in this case, of approving not the settlement agreement itself, but the *dismissal of the relator's claims* in exchange for payment.

Thus, while Baxter and Ven-A-Care agreed upon a covered-conduct definition, the United States, in consenting to the settlement, agreed to the "dismissal with prejudice **of claims in the above-captioned action** . . . pursuant to, and limited by, the Settlement Agreement and Release[.]" Emphasis supplied. Those claims simply could not have included Advate, *because* Ven-A-Care *had no Advate claims.* And if inconceivably there was a meeting of the minds between Ven-A-Care and Baxter to sneak language into the settlement which exceeded the terms of the Ven-A-Care complaint in order to vitiate this case, the resulting agreement would, to that extent, contravene public policy: Under federal common law, "a promise is unenforceable if the interest in its enforcement is outweighed in the circumstance by a public policy harmed by enforcement of the agreement." *Town of Newton v. Rumery*, 480 U.S. 386, 392 (1987). Indeed, Baxter has made no attempt to show that the United States was informed that the settlement agreement which was presented to it impacted the government's interest in this case, and a *sub silentio* "settlement" of this case without notice to the United States is precisely as inconsistent with public policy as the *sub silentio* neglect of the federal interest in *Health Possibilities*.[3]

[3] The settlement agreement between Ven-A-Care and Baxter includes a severability clause which contemplates that the Court may find "any of the release provisions . . . unenforceable," giving Ven-A-

A recent decision involving two cases brought against Motorola under the *qui tam* provision of the false marking statute, 35 U.S.C. § 292(a), is both interesting and instructive. In *Promote Innovation, LLC v. Motorola, Inc*., 2011 WL 3610049 (E.D. Tex., August 11, 2011), plaintiff Promote Innovation sued Motorola for false patent marking under "at least U.S. Patent Nos. 4,577,216" and two others. Plaintiff Setarah then sued Motorola on behalf of the United States regarding false making with respect to two patents, called "the '114 and '901 patents." *Id*., slip op. At 3. Promote and Motorola entered into a "broad settlement that encompasses" the '114 and '901 patents. *Id*. That settlement "uses broad language to purportedly include the '114 and '901 patents without explicitly naming [them]." *Id.*

Finally, while Relators recognize that as between the parties, releases are broadly construed on the assumption that the parties to release sought fully peace, that doctrine has no place in the context of a summary-judgment motion in litigation collateral to the case in which the release was entered. Here, Baxter has the burden of demonstrating that there are no material facts regarding the intent of the *United States* not it or Ven-A-Care to release the claims of the *United States* regarding Advate. This cannot be done.

Simply put, the reference to "Labeler Code 00944" in the settlement agreement between Ven-A-Care and Baxter must, in order to be consistent with the requirements of the False Claims Act and public policy, be read as "Labeler Code 00944 drugs identified in the Ven-A-Care Complaint."

Care the right to re-file and litigate its claims if, in such event, Baxter chose to deem the settlement void. Doc. 7831-1 at ¶ 20. Thus, the parties to the Ven-A-Care settlement negotiated in such a manner as to preclude the automatic nullification of the settlement in the event that Baxter's attempt to eviscerate this case failed. This is consistent with holdings that district courts, as part of their power to approve or disapprove settlements, may reconcile them with the requirements of the Act. *E.g*., *United States ex rel. Sharma v. University of Southern California*, 217 F.3d 1141, 1145 (9th Cir. 2000).

B. **Baxter Has Not Established That the Government, Especially the State Medicaid Directors, Knew that It Was Fraudulently Creating Mega-Spreads of Nearly Two Hundred Per Cent.**

In its "Memorandum Of Baxter Healthcare Corporation In Support Of Its Motion For Partial Summary Judgment" (Baxter Memorandum - starting at page 4) Baxter contends that: "[T]he Government's detailed knowledge concerning blood-clotting therapy AWPs, and HHS's and Congress's explicit acquiescence in indeed approval of the use of allegedly inflated AWPs for reimbursement of those therapies." provides Baxter with a comprehensive defense to the claims of Ms. Sun and Mr. Hamilton.

Notwithstanding the highly factual nature of any inquiry to support the assertion of "explicit acquiescence" by the Government and Congress, Baxter nonetheless spends the next 5 pages of its Memorandum seeking summary disposition of the Sun/Hamilton claims based on an array of documents drawn from various public records which Baxter claims supports its broad assertions. However, just as Baxter overreaches with respect to its argument regarding the scope of the Government's release in Ven-A-Care it overreaches with respect to this argument as well. It is simply not appropriate for Baxter to seek or be granted Summary Judgment based on Baxter's one sided reading of a collection of miscellaneous material that requires further factual inquiry. Significantly, Baxter's assertion that the various documents it relies on to support its position that the Government and Congress gave Baxter carte blanche to change whatever it wished for Advate is not supported by the content of the documents themselves.

(1) Government Knowledge Does Not Negate the Falsity of a Claim

Baxter claims that because the Government was aware that AWPs had historically been inflated but relied on them as a basis for pricing regardless of this knowledge, that no claims for payment based on AWP are false. This is patently untrue, and the weight of federal case law belies this claim. This Court has acknowledged that "As to falsity, 'there appears to be an emerging consensus (not without significant authority to the contrary) that it is not negated by government knowledge" *Massachusetts v. Mylan Labs*, 608 F Supp. 2d 127 at 148 (D. Mass, 2008), quoting John T. Boese, Civil False Claims and Qui Tam Actions §2.03 [F] (3d ed. 2008). The Court goes on to state that "'what constitutes the offense is not intent to deceive but knowing presentation of a claim that is either 'fraudulent' or simply 'false'…That the relevant government officials know of the falsity is not in itself a defense'" *Id*, quoting *US ex rel. Hagood v. Sonoma County Water Agency,* 929 F. 2d 1416, 1421 (9th Cir 1991). Many other courts across the circuits that have concurred with this holding. *Id*. See also *United States ex rel.Kreindler & Kreindler v. United Techs. Corp*., 985 F.2d 1148, 1156 (2d Cir. 1993); *United States ex rel. Becker v. Westinghouse Savannah River Co*., 305 F.3d 284, 289 (4th Cir. 2002); *Tyger Constr. Co. v. United States,* 28 Fed. Cl. 35, 60 (Fed. Cl. 1993); *United States ex rel. Mayman v. Martin Marietta Corp*., 894 F. Supp. 218, 223 (D. Md. 1995).

Even where courts have held that government knowledge does negate the falsity of a claim, the government in these cases must "possess knowledge of the actual true facts of the claim, not simply knowledge that the claim is generally false; some have further required that the government actually approve of those true facts" *Mylan Labs* at 149. Therefore, in order for the government knowledge defense to be valid, the defendant must show that the "government

knows and approves of the *particulars of a claim* for payment before that claim is presented" *Id* quoting *US ex rel. Durcholz c. FKW Inc*., 189 F. 3d 542, 545 (7th Cir, 1999) (emphasis added). See also *Becker, supra* ("government's *full knowledge of the material facts* underlying [a defendant's representations]" negates scienter and falsity); *US ex rel. Butler v. Hughes Helicopters Inc*., 71 F. 3d 321, 327 (9th Cir., 1995) ("where defendant and government 'so completely cooperated and shared all information' claims could not be knowingly false"); *US ex rel. Ven-A-Care of the Fla. Keys Inc.v. Abbot Labs,* 254 F.R.D. 35, 40-43 (D. Mass, 2008) (quoting *Durcholz, Becker*, and *Butler, supra*).

(2) Baxter Has Failed to Establish Government Knowledge of its Mega-Spreads on Advate and Recombinate

As this Court has previously found the expected cost of storing and administering the drugs would require a margin of no greater than 20-25%. [In re Pharm. Manufacturer Average Wholesale Price Litig. 491 F. Supp. 2d, 20, at 32 (D. Mass. 2007).

Moreover, to the extent that any manipulation of the Average Wholesale Price was to be "expected," that manipulation should have been no greater than 30% of the pharmacy acquisition cost.

Yet the core of the relators' allegations detail a specific scheme wherein Baxter defrauded Medicare and Medicaid by falsely reporting a WAC that created a spread that was significantly greater than industry average. *Sun/Hamilton Second Amended Complaint (S/H 2AC)* ¶47. In fact, the spread on Advate 192% (*Hamilton Decla,* ¶4) and on Recombinate was 186% (*Hamilton Decla., ¶5).* These mega-spreads are many times higher than spreads in the industry in general, and Baxter offer no evidence that state Medicaid directors had any idea of

this state of affairs. In fact, Baxter's evidence (*Patel*, *Decla., Ex. BB*) does not concern the Medicaid program at all. It is a memo to the Medicare contractors. Nowhere is there any discussion that state Medicaid officials had any inkling of the actual state of affairs. Although the Government may have had a general knowledge of the existence of AWP spreads, there is no evidence that they were aware of, nor that they approved of the "particulars of the claims" being presented by Baxter in this case.

(3). General Knowledge of Industry Wrongdoing Does Not Mean the Goverrnment Has Notice of a Specific Fraud Perpetrated by a Specific Defendant.

The fact that the Government has general knowledge that fraud is taking place does not constitute a public disclosure for purposes of putting the government on notice of a specific instance of fraud perpetrated by a specific defendant. See *In re Pharm. Indus. AWP Litig*: *US ex rel. Ven-a-Care of the Fla. Keys v. Actavis Mid Atlantic LLC,* 659 F. Supp 2d 262, 267-268, quoting *Cooper v. Blue Cross and Blue Shield of Fla., Inc*., 19 F.3d 562, 566 (11th Cir. 1994) (requiring allegations specific to particular defendants because "[t]o hold otherwise would preclude any *qui tam* suit once widespread - but not universal - fraud in an industry was revealed. The government often knows on a general level that fraud is taking place . . . [b]ut it has difficulty identifying all of the individual actors engaged in the fraudulent activity")

(4). The Government did not validate cross-subsidization of the treatment of hemophilia to cover ancillary expenses incurred by providers.

In its brief, Baxter contends: "In addition, providers incur additional costs in ancillary supplies such as needles, syringes, and tourniquets necessary for infusing blood-clotting therapies to the hemophilia community that are not reimbursed by Medicare. *Id*. HHS and

many health professionals feared that if these costs were not reimbursed in some fashion, providers would be unwilling to continue providing the therapies at necessary levels and hemophiliacs might suffer as a result." ("Baxter Memorandum, p.5) However, the record Baxter cites to is to the contrary:

> "A drug reimbursement system should be based on real prices available in the marketplace. Physicians and suppliers, including pharmacies, should be fairly reimbursed and at levels that ensure that the drugs are accessible. If reimbursement is set too low, some beneficiaries may not be able to obtain needed prescription drugs. We recognize that some physician groups have raised concerns about Medicare's attempts to lower reimbursement for prescription drugs. Specifically, these physician groups say that overpayments for prescription drags simply make up for inadequate payments for their practice costs. We agree that physicians need to be properly reimbursed for patient care. *However, we do not believe that the payment of artificially inflated drug prices is an appropriate mechanism to compensate them.*" (emphasis supplied)
>
> *Medicare Payments, for Currently Covered Prescription Drugs,* Before the H. Subcomm. on Health of the Comm. on Ways and Means, 107th Cong. (2002) (statement of George Reeb, Assistant Inspector General, Centers for Medicare and Medicaid Audits, Department of Health and Human Services, Office of Inspector General). Page 5.

See Exhibit S, Declaration of Shamir Patel In Support of Baxter Healthcare Corporation's Motion for Partial Summary Judgment.

Similarly, a GAO Report dated January 10, 2003, also cited by Baxter notes:

> "Although providers contended that this overpayment was necessary to compensate for underpayment for other services, we concluded that Medicare should not rely on potential overpayments for some services to offset potential inadequate payments for other services.

> (U.S. GOVERNMENT ACCOUNTABILITY OFFICE, GAO-03-184, MEDICARE: PAYMENT FOR BLOOD CLOTTING FACTOR EXCEEDS PROVIDERS' ACQUISITION COST (2003), Pages 1-2).

See Exhibit X, Declaration of Shamir Patel In Support of Baxter Healthcare Corporation's Motion for Partial Summary Judgment.

(5) The factual record of practices in the drug industry do not support Baxter's position.

Lastly, the factual record when the very issue of cross-subsidization was litigated also does not support Baxter's position.

> "One oft-cited justification for inflating the AWP above true market costs is that reimbursement for the physician services rendered in administering the drugs often fell short of the costs of administration incurred by the physicians. (Bell T1 Aff. ¶ 7.) For example, CMS acknowledged that "Medicare payments related to the provision of chemotherapy drugs and clotting factors used to treat hemophilia and similar disorders are inadequate." (DX 1090 at 0059.) Accordingly, doctors used the profit margin on the drugs to cross-subsidize administration fees and other risks (like spoilage) associated with physician-administered drugs. (Bell T1 Aff. ¶ 75.) At trial, there was no evidence about the extent of a shortfall in the costs of administration of the drugs in question in this *38 litigation. *Moreover, there was no evidence that any m argin over the 20 to 25 percent industry-wide formula was needed to compensate doctors for their costs of administration for these drugs and risks like spoilage. Significantly, the pharmaceutical companies marketed the spread by demonstrating to the doctor that he would make a profit on the drug, not by demonstrating that the drug would cover costs of administration or other risks.*" (emphasis supplied)

In re Pharm. Manufacturer Average Wholesale Price Litig. 491 F. Supp. 2d, 20, at 37-38. (D. Mass. 2007).

On balance, it makes little sense to argue that the Government and Congress gave drug companies carte blanche to seek reimbursement at any price the drug manufacturer chooses to

establish. All Medicaid programs require that drug companies be reimbursed without artificially inflating prices. The scheme that Ms. Sun and Mr. Hamilton allege is that Baxter used a price that it charged to a very small percentage of its customers as its actual price to its entire universe of customers who bought Advate. This practice by Baxter necessarily inflated the costs that Baxter charged Medicaid recipients and to suggest that the Government and Congress acquiesced in this practice is simply not born out in the record Baxter presents, nor by common-sense. Nowhere in Baxter's material is such a scheme acknowledged, let alone validated. Relators do not believe that Baxter's position is to be credited. However, out of an abundance of caution, Relators have submitted a declaration of counse pursuant to Fed. R. Civ. Pro 56(f) explaining the discovery they seek to establish that the Medicaid programs did not know of the mega-spreads, and did not know that the spreads were continuing long after any claimed need for "cross subsidization" of provider costs had ended in 2005.[4]

c. **The Sun / Hamilton Allegations About Recombinate Are Wholly Separate from the Ven-A-Care Claims and Could Not Have Been Encompassed in the Ven-A-Care Release**

As noted *supra*, this Court has rightly rejected blunder-buss-style claims about industry-wide practices and requires that the claims be plead with specificity. *In re. Pharm. Indus. AWP Litigation*, 293 F.Supp.2d 194 (D. Mass. 2003). Where Ven-A-Care's allegations regarding Recombinate merely listed four or five possibly fraudulent schemes, any one of which may or may not have occurred, as is the case for all of the Baxter products Ven-A-Care named, the Sun/Hamilton relators have quite specifically explained their detailed knowledge of a scheme regarding the presentation of list prices to FirstData Bank a scheme which could not have even

[4] Relators will shortly file a motion seeking time to complete the discovery they will have noticed..

existed at the tie Ven-A-Care filed its complaint. *Sun/Hamilton*'s complaint detailed this new species of fraud, which could not have existed before the DOJ / First Databank consent decree, and which therefore could not be encompassed by Ven-A-Care's complaint. It is questionable whether Ven-A-Care has properly established *any* claims about Recombinate. At the very least, the allegations brought forth by Sun/Hamilton are distinctly pled, must be distinctly analyed, and form the basis for a new and separate set of damages.

III. **CONCLUSION**

This motion must be denied. It is apparent that the Government never intended to release claims about Advate and never did release them. It is equally manifest that there is no evidence that government decision-makers, especially state Medicaid directors, had any Claims of knowledge, much less acquiescence, could not be further from the truth. appreciation of the manipulated mega-spread Baxter had awarded itself.

Dated: November 14, 2011

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CERTIFICATION OF SERVICE

I hereby certify that I caused a true and correct copy of the foregoing RELATORS' MEMORANDUM IN OPPOSITION TO DEFENDANT BAXTER HEALTHCARE CORPORATION'S MOTION FOR PARTIAL SUMMARY JUDGMENT to be served on all counsel of record via electronic service by sending a copy to LexisNexis File & Serve for posting and notification to all parties on November 14, 2011.

/s/ Mark Allen Kleiman
MARK ALLEN KLEIMAN